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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

O'HAGAN et al.

Serial No.: 09/935,466 Group Art Unit: 1648

Filing Date: August 20, 2001 Examiner: S. Brown

Title: USE OF MICROPARTICLES COMBINED WITH SUBMICRON OIL-IN-WATER EMULSIONS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. The information includes:

United States Patent No. 5,629,167 issued May 13, 1997 to Ratti;

United States Patent No. 5,783,567, issued July 21, 1998 to Hedley et al.;

United States Patent No. 5,869,103, issued February 9, 1999 to Yeh et al.;

United States Patent No. 5,961,970, issued October 5, 1999 to Lowell et al.;

International Patent No. WO 90/14837, published December 13, 1990;

International Patent No. WO 92/00081, published January 9, 1992;

International Patent No. WO 97/02810, published January 30, 1997;

European Publication No. EP 0 399 843 B1, published July 13, 1994;

Esparza et al., "Parameters Affecting the Immunogenicity of Microencapsulated Tetanus Toxoid," *Vaccine* 10(10):714-720 (1992);

A.S. Fauci, "Update on the Status of Vaccine Development," *Pediatric Aids and HIV Infection: Fetus to Adolescent* 5(1):47-58 (1994);

Higgins et al., "MF59 Adjuvant Enhances the Immunogenicity of Influenza Vaccine in Both Young and Old Mice," *Vaccine* 14(6):478-484 (1996);

Moore et al., "Immunization with a Soluble Recombinant HIV Protein Entrapped in Biodegradable Microparticles Induces HIV-Specific $CD8^+$ Cytotoxic T Lymphocytes and $CD4^+$ Th1 Cells," *Vaccine* 13(18):1741-1749 (1995);

O'Hagan et al., "Biodegradable Microparticles for Oral Immunization," *Vaccine* 11:149-154 (1993);

O'Hagan, "Recent Advances in Vaccine Adjuvants for Systemic and Mucosal Administration," *J. Pharm. Pharmacol* 49:1-10 (1997);

Ott et al., "Design and Evaluation of a Safe and Potent Adjuvant for Human Vaccines," *Vaccine Design: The Subunit and Adjuvant Approach* (Powell, M.F. and Newman, M.J. eds.) Plenum Press, New York, pp. 277-296 (1995);

Sanchez-Pescador et al., "The Effect of Adjuvants on the Efficacy of a Recombinant Herpes Simplex Virus Glycoprotein Vaccine," *The Journal of Immunol.* 141(5):1720-1727 (1988); and

Vordermeier et al., "Synthetic Delivery System for Tuberculosis Vaccines: Immunological Evaluation of the M. *Tuberculosis* 38 kDa Protein Entrapped in Biodegradable PLG Microparticles," *Vaccine* 13(16):1576-1582 (1995).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional

information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 2/28/02

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